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Annual Survey of Laboratory Testing Practices for *C. difficile* Infection

CDC's Emerging Infections Program - *Clostridioides difficile* Infection Surveillance

Section 1: Laboratory Information

To be completed by surveillance officer

LABID#: _____

Completed By: _____

Position of the staff who responded to the survey:

- ◯ Laboratory Supervisor
- ◯ Microbiology Supervisor
- ◯ Other
  Specify: _____

Date survey was completed: _____ /_____ /_____

Is this a new laboratory?

- ◯ Yes
- ◯ No
  Year added to surveillance: _____

Is this lab in another EIP site?

- ◯ Yes
  What state? _____
  LabID in other EIP site: _____
- ◯ No

Is this lab participating in surveillance?

- ◯ Yes
- ◯ No

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How often do you receive line lists from this lab?

- ◯ Daily
- ◯ Weekly
- ◯ Monthly
- ◯ Annually
- ◯ Never
- ◯ Other

  Specify: _____

How do you receive line lists from this lab?

- ◯ Electronic laboratory reporting (e.g. HL7 messaging)
- ◯ Fax
- ◯ Email
- ◯ Mail
- ◯ Secure file transfer
- ◯ Other

  Specify: _____

Do you receive specimens from this lab?

- ◯ Yes
- ◯ No

Was this lab audited in 2018?

- ◯ Yes, in person
- ◯ Yes, not in person
- ◯ No, not in catchment
- ◯ No, not audited

  Specify reason: _____

Is this a private, commercial lab (e.g. Quest or LabCorp)?

- ◯ Yes
- ◯ No

Types of facilities in your catchment area served by this lab (select all that apply):

- ◯ Hospitals
- ◯ LTACHs
- ◯ LTCFs
- ◯ Outpatient facilities

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Section 2: Survey

To be completed by lab personnel

Offsite Testing

1. Does your laboratory ever send specimens off-site for *Clostridioides difficile* testing? *(Choose one)*

- ◯ Always (no onsite testing performed)
  LabID of Offsite Lab: _____
- ◯ Regularly, as part of standard testing algorithm
  LabID of Offsite Lab: _____
  Which tests are done offsite, and at which point in the testing algorithm?
  _____
- ◯ Not regularly, but when a test ordered by a physician cannot be performed onsite
  Specify tests performed offsite: _____
- ◯ Never (All testing performed onsite)
- ◯ Unknown
- ◯ Other
  Specify: _____

Testing Routine

2. What type and order of testing is routinely used by your laboratory in standard testing for *C.difficile*?
(Enter letter from choices below; choose only one option for each line of testing)

1st line of testing: _____ **2nd line of testing:** _____ **3rd line of testing:** _____

A. EIA Toxin A and B
B. EIA for Toxin A only
C. EIA for Toxin B only
D. EIA Antigen (GDH)
E. EIA Toxin A/B and Antigen (Simultaneous testing)
F. EIA Other
Specify other EIA type: _____
G. Nucleic Acid Amplification (e.g. PCR, Illumigene, Luminex)
H. Culture
I. Cytotoxin
J. Other
Specify other test type: _____
K. No one routine test; clients can order from among several tests
Specify types: _____
L. None

2a. Which specimens are used during your 2nd line of testing? *(Choose one)*

- ◯ Positive by the 1st line of testing

- ◯ Negative by the 1st line of testing
- ◯ Specimens with discordant results (e.g. EIA+/GDH- or GDH+/EIA-)
- ◯ All specimens
- ◯ Do not use 2nd line of testing *(go to question 3a)*

2b. Which specimens are used during your 3rd line of testing? *(Choose one)*

- ◯ Positive by the 2nd line of testing
- ◯ Negative by the 2nd line of testing
- ◯ Specimens with discordant results (e.g. EIA+/GDH- or GDH+/EIA-)
- ◯ All specimens
- ◯ Do not use 3rd line of testing *(go to question 3a)*

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Testing Kits

3a. Which EIA test kit is currently used by your laboratory? *(Check all that apply)*

- □ Premier (Meridian) Toxins A & B
- □ Premier (Meridian) Toxin A
- □ Remel ProSpecT Toxins A & B
- □ TechLab Toxins A & B
- □ Inverness Medical/Wampole Toxins A & B QuikCheck
- □ Inverness Medical/Wampole QuikCheck Complete (Toxins A & B and Antigen)
- □ Antigen Testing
  Specify antigen testing kit name/manufacturer: _____
- □ Other
  Specify other kit name/manufacturer: _____
- □ N/A (Do not use EIA testing)

3b. Which Nucleic Acid Amplification test is currently used by your laboratory? *(Check all that apply)*

- □ BD-GeneOhm C. difficile
- □ Cepheid Xpert C. difficile
- □ Meridian Illumigene
- □ Prodesse (Gen-Probe) Progastro CD
- □ Luminex xTAG GPP
- □ Other
  Specify other test: _____
- □ N/A (Do not use nucleic acid amplification)

Testing Codes

4. What are the testing codes associated with the tests your lab currently uses?

Specify: _____

Laboratory Algorithm

5. Has your lab testing algorithm for *C. difficile* changed since January 1, 2018?

- ◯ Yes
  What date did this change occur? _____ / _____ / _____
- ◯ No

(*If Yes was checked, go on to 5a, but please do not forget to ask Q7 at the end of the survey*)

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5a. *(If yes)* **What was your previous type and order of testing?**
(Enter letter from choices below; choose only one option for each line of testing)

1st line of testing: _____ 2nd line of testing: _____ 3rd line of testing: _____

A. EIA Toxin A and B
B. EIA for Toxin A only
C. EIA for Toxin B only
D. EIA Antigen (GDH)
E. EIA Toxin A/B and Antigen (Simultaneous testing)
F. EIA Other
Specify other EIA type: _____
G. Nucleic Acid Amplification (e.g. PCR, Illumigene, Luminex)
H. Culture
I. Cytotoxin
J. Other
Specify other test type: _____
K. No one routine test; clients can order from among several tests
Specify types: _____
L. None

5b. Which specimens were used during your 2nd line of testing? *(Choose one)*

◯ Positive by the 1st line of testing
◯ Negative by the 1st line of testing
◯ Specimens with discordant results (e.g. EIA +/GDH- or GDH+/EIA-)
◯ All specimens
◯ Do not use 2nd line of testing *(go to question 6)*

5c. Which specimens were used during your 3rd line of testing? *(Choose one)*

◯ Positive by the 2nd line of testing
◯ Negative by the 2nd line of testing
◯ Specimens with discordant results (e.g. EIA+/GDH- or GDH+/EIA-)
◯ All specimens
◯ Do not use 3rd line of testing *(go to question 6)*

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Laboratory Policies

6. Does your lab have a policy to reject stool specimens for *C. difficile* testing? *(Read all options. Check all that apply)*

- □ Yes, when stools are formed (formed stools are defined as stools that do NOT take the shape of the container)
- □ Yes, if there is a stool specimen already positive within 24 hrs of a new stool specimen
- □ Yes, if there is a stool specimen already positive within 48 hrs of a new stool specimen
- □ Yes, if there is a stool specimen that tested negative for *C. difficile* within 48 hours of a new stool specimen
- □ Yes, will not accept more than one stool specimen in a 24 hr period
- □ No rejection policy
- □ Other rejection policies

  Specify other rejection policy: _____

6a. Has your rejection policy for stool specimens changed since January 1, 2018?

- ◯ Yes

  What date did this change occur? _____ / _____ / _____

  Specify changes: _____
- ◯ No

For labs that changed testing practices in the past year

7. Since your laboratory changed its testing algorithm for CDI diagnosis in the past year and this may have had an impact in the number of positive specimens, it is very important for us to have information on the number of stool samples tested for *C. difficile* and the number of stool samples positive for *C. difficile* in the 3 months prior to and the 3 months following the change in testing methodology.

	3 months prior (mm/yyyy)	2 months prior (mm/yyyy)	1 month prior (mm/yyyy)	1 month post (mm/yyyy)	2 months post (mm/yyyy)	3 months post (mm/yyyy)
Stool samples tested for *C.diff*						
Stool samples positive for *C.diff*						

If your lab phased in a new lab diagnostic test during a particular month and there is no specific date, please fill out the table below starting with the month prior to the switch (e.g. if switch was in July, fill out the pre period with data from months April through June and the post-period with data from August through October).

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Appendix: Common *C. difficile* Test Kit Names and Manufactures

EIA Toxin A & B

Wampole* Toxin A/B Quik Chek
Techlab* *C. difficile* Toxin A/B II
BioMerieux Vidas *C. difficile* Toxin A/B
Meridian Immunocard Toxin A/B
Meridian Premier Toxin A/B
Remel Xpect *C. difficile* Toxin A/B
Remel ProSpecT Toxin A/B

EIA Antigen (GDH)

Wampole* *C. difficile* Chek-60
Wampole* *C. difficile* Quik Chek
Meridian Immunocard *C. difficile*

EIA Toxin A/B and Antigen (Simultaneous Testing)

Wampole* *C. difficile* Quik Chek Complete

Nucleic Acid Amplification

BD-GeneOhm *C. difficile*
Cepheid Xpert *C. difficile*
Great Basin Portrait Toxigenic *C. difficile* Assay
Luminex xTAG Gastrointestinal Pathogen Panel (xTAG GPP)
Meridian BioScience Illumigene
Nanosphere Verigene SP
Prodesse (Gen-Probe) Progastro CD
Quidel AmpliVue *C. difficile* Assay

EIA for Toxin B Only

Alere* *C. difficile* Toxin B

*Techlab, Inverness Medical, Alere, Wampole may be used interchangeably for these test kits